

SAT Report

PMN Number: L-14-0047

SAT Date: 12/3/2013

Print Date: 11/26/2014

Related cases:

Concern levels:

Type of Concern:	<u>Health</u>	<u>Eco</u>	<u>Comments</u>
Level of Concern:	1-2	3	

<u>Persistence</u>	<u>Bioaccum</u>	<u>Toxicity</u>	<u>Comments</u>
3	1	1	
		Awaiting	
		Human Health	
		Entry	
		Awaiting	
		Human Health	
		Entry	
		Awaiting	
		Human Health	
		Entry	

Exposure Based Review:

Health: No

Ecotox: No

Routes of exposure:

Health: Dermal Drinking Water Inhalation

Ecotox: All releases to water

Fate: ;

Keywords:

Keywords:

Summary of Assessment:

Fate:

Fate Summary

Liquid with MP < 25 C (E)
log Kow = 4.08 (M), 2.38 (E)
S = 225 mg/L at 25 C (E)

VP < 1.0E-6 torr at 25 C (E)

BP > 400 C (E)

H < 1.00E-8 (E)

log Koc = 5.05 (E)

log Fish BCF = 1.24 (E)

log Fish BAF = 1.09 (E)

POTW removal (%) = 0-25 via sorption; [REDACTED]: OECD 306(Biodeg in Seawater, Closed Btl): 2%/28d, 3%/60d. L-14-0047: OECD 306(Biodeg in Seawater, Closed Btl):2%/28d, 5%/60d.

Time for complete ultimate aerobic biodeg > mo

Sorption to soils/sediments = low - moderate

PBT Potential: P3B1

*CEB FATE: Migration to ground water = rapid

Health:

Health Summary: Absorption of the low molecular weight fraction [REDACTED] is poor all routes, based on physical/chemical properties. There are concerns for solvent irritation to the eye, skin, and mucous membranes and for solvent neurotoxicity.

Ecotox:

Test Organism	Test Type	Test End Point	Predicted	Measured	Comments
fish	96-h	LC50	1.3		
daphnid	48-h	LC50	0.23		
green algal	96-h	EC50	0.29		
fish	—	chronic value	0.26		[REDACTED]
daphnid	—	chronic value	0.046		[REDACTED]
algal	—	chronic value	0.22		
Sewage Sludge	3-h	EC50	—		
Sewage Sludge	—	Chronic Value	—		

Ecotox Values Comments:

Factors	Values	Comments
Assessment Factor	10	
Concentration of Concern (ppb)	5	
SARs	nonionic surfactants	
SAR Class	surfactant-nonionic [REDACTED]	
Ecotox Category		

Ecotox Factors Comments:

SAT Chair: J. Kwiat, 564-7653

Focus Report
New Chemicals Program
PMN Number: L-14-0047

Focus Date: 12/09/2013 12:00:00 AM Report Status: Completed
Consolidated Set:
Focus Chair: Loraine Passe Contractor: Olga Svetlitskaya

I. Notice Information

Submitter: Resman USA CAS Number: [REDACTED]
Chemical Name: [REDACTED]

Use: Chemical tracer for production monitoring in oil and gas wells. [REDACTED]

Other Uses: [REDACTED]

PV-Max: 10,000 Kg/yr Binding Option: No
Manufacture: Import: X

II. SAT Results

(1) Health Rating: 1-2 Eco Rating: 3 Comments: ;

Occupational: 1C Non-Occupational: 1 Environmental: 1

(1) PBT: 3 1 1 Comments:

III. OTHER FACTORS

Categories:

Health Chemical Category: Ecotox Category: nonionic surfactants

Related Cases/Regulatory History:

Health related Cases:

Ecotox Related Cases: Analogs: [REDACTED]

Regulatory History: [REDACTED]
- FOCUS DROP
- FOCUS DROP
- FOCUS DROP
- FOCUS DROP

MSDS/Label Information:

MSDS: Yes Label: No
General Equipment: gloves (selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it) / Safety glasses with side-shields conforming to EN166. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN166 (EU). / Impervious clothing.
Respirator: For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEKP2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Health Effects: Inhalation of dust from the break down products may however cause headaches or respiratory irritation. Prolonged or repeated exposure can irritate eyes and skin.
TLV/PEL (PMN or raw material): - none established.
LVEPPE: Solid form, PPE: gloves, eye protection

Exposure Based Information:

Exposure Based Review: N Exposure Based Review (Health): N
Exposure Based Review (Eco): N Exposure Based (Occupational): No
Exposure Based Review Exposure Based (Environmental):
(Non Occupational):

IV. Summary of SAT Assessment

Fate:

Fate Summary:

L-14-0046-47

FATE: Estimations for typical [REDACTED]

Liquid with MP < 25 C (E)

log Kow = 4.08 (M), 2.38 (E)

S = 225 mg/L at 25 C (E)

VP < 1.0E-6 torr at 25 C (E)

BP > 400 C (E)

H < 1.00E-8 (E)

log Koc = 5.05 (E)

log Fish BCF = 1.24 (E)

log Fish BAF = 1.09 (E)

POTW removal (%) = 0-25 via sorption; L-14-0046: OECD 306(Biodeg in Seawater, Closed

Btl): 2%/28d, 3%/60d. L-14-0047: OECD 306(Biodeg in Seawater, Closed Btl):2%/28d, 5%/60d.

Time for complete ultimate aerobic biodeg > mo

Sorption to soils/sediments = low - moderate

PBT Potential: P3B1

*CEB FATE: Migration to ground water = rapid

Health:

Health Summary:

Absorption of the low molecular weight fraction [REDACTED] is poor all routes, based on physical/chemical properties. There are concerns for [REDACTED] irritation to the eye, skin, and mucous membranes and for [REDACTED] neurotoxicity.

Ecotox:

Ecotox Values:

Fish 96-h LC50: 1.3(P)

Daphnid 48-h LC50: 0.23(P)

Green algal 96-h EC50: 0.29(P)

Fish Chronic Value: 0.26(P)

Daphnid ChV: 0.046(P)

Algal ChV: 0.22(P)

Ecotox values comments: Predictions are based on SARs for [REDACTED]; SAR chemical class =

[REDACTED]; S = 2.1 mg/L @ 20 C (P); liquid with unknown mp (P); pH7; effective concentrations based on 100% active ingredients and mean measured concentrations; DW hardness <150.0 mg/L as CaCO3; and DW TOC <2.0 mg/L;

Ecotoxicity Test Data Results: L-14-0047; [REDACTED]

Fish Ecotoxicity Test:

Environmental Enterprises USA, Inc. conducted a 7-day larval survival and growth test in the inland silverside (*Menidia beryllina*) with L-14-0047 [REDACTED] under semi-static conditions with daily renewal. This study was reported to follow EPA-821-R-02-014: Method 1006. Five replicates of eight *M. beryllina* were exposed to a negative control (synthetic seawater) or the test substance prepared as water accommodated fractions (WAFs) at nominal concentrations of 0.0005, 0.0050, 0.0500, 0.5000 and 1.0000 parts per quadrillion (ppq). To prepare the test solutions, a stock solution of 5 g test substance per one thousand milliliters dilution water was prepared in a sealed 2 L glass flask and mixed for 24 hours on magnetic stirrers using 1/2" diameter by 3" long stir bars. The depth of the vortex of each mixing treatment was adjusted to approximately 1/3 the total depth of the solution. After mixing for 24 hours, each treatment was allowed to settle for 60 minutes. After settling, the test material (WAF) for each treatment was siphoned from approximately 1.5" below the dilution water surface: the interface of the water soluble and insoluble fraction. An aliquot of this stock solution was diluted with synthetic seawater until a 0.625 ppt stock solution was prepared. This stock solution was used daily to prepare test

concentrations. The test temperature was maintained at $25 \pm 1^\circ\text{C}$. Dilution water salinity was 25 ‰. Survival and growth of *M. beryllina* larvae exposed to the test substance was not reduced significantly at any concentration tested. The 7-day NOEC and LOEC values were 1.0000 ppq WAF and > 1.0000 ppq WAF, respectively, for both survival and growth. This is not an acceptable test for several reasons. It is not clear why 1 ppq was the highest concentration tested. Appendixes A-E were not provided with the submission to determine the water chemistry values, dry weight values, summary statistics, preparation of the test concentrations, etc. They are reported to be in the appendixes. It is not possible to accept only part of this data. Ninety six hour EC50 values were not reported within this 7 day study report. Since a 7 day ecotoxicity study is not a chronic study for OCSPP, the LOEC and NOEC were not used for chronic endpoints.

7-day NOEC (survival and growth) = 1.0000 ppq WAF
 7-day LOEC (survival and growth) > 1.0000 ppq WAF

Aquatic Invertebrates Ectotoxicity Test:

(1) Eurofins Norsk Miljøanalyse conducted a 48-hour toxicity test in the marine copepod *Acartia tonsa* with L-14-0047 [REDACTED] under static conditions. This study was reported to follow ISO 14669-1999: Water quality – Determination of acute lethal toxicity to marine copepods (Copepoda, Crustacea). Following preliminary tests, four replicates of five *A. tonsa* were exposed to the test substance as water accommodated fractions (WAFs) at nominal concentrations of 1.0, 1.8, 3.4, 5.6, 10.2, 18.2 and 32.0 mg/L. Additionally, six replicates of five *A. tonsa* were exposed to a blank control (growth medium with no LVE). WAFs were prepared individually by stirring appropriate amounts of the test substance in growth medium (according to ISO 14442:2006). The solutions were stirred with a spin-bar for 22 hours with a speed which formed a vortex one-third of the depth of the fluid content, followed by a standstill for about 2 hours. Closed aspirator bottles were used, and samples for testing were drawn off through a drain port near the bottom of the bottle. Over the course of testing, temperature ranged from $19.1 - 21.0^\circ\text{C}$ and dissolved oxygen ranged from 7.1 – 8.1 mg/L. At the start of the test, the pH ranged from 8.1 – 8.2. The dilution water had a salinity of 32 ‰. The calculated loading rate was approximately 200 organisms/L. Percent mortality at 0 (control), 1.0, 1.8, 3.4, 5.6, 10.2, 18.2 and 32.0 mg/L was 0%, 100%, 100%, 100%, 100%, 100%, 100% and 100% within 48-hours, respectively. Complete lethality occurred within one hour at the highest test concentration; therefore, dissolved oxygen and pH were only recorded once. Based on nominal concentrations, the 48-hour LC50 was less than 1.0 mg/L WAF. This is not an acceptable study since all organisms at all test concentrations died by the end of the test. EPA recommends initially to conduct a range finding study prior to future definitive toxicity test concentration determination.

48-hour LC50 < 1.0 mg/L WAF

(2) Eurofins Norsk Miljøanalyse AS conducted a 10-day toxicity test with the marine amphipod *Corophium volutator* with L-14-0047 [REDACTED] under static conditions. This study was reported to follow “OSPAR Protocols on Methods for Testing of Chemicals Used in the Offshore Oil Industry. OSPAR Commission 2005. Part A: Sediment Bioassay Using an Amphipod *Corophium* sp.” Two or three replicates of ten *C. volutator* were exposed to the test substance at nominal concentrations of 5.4, 10.3, 17.8 and 34.9 mg/kg sediment dry weight. Six replicates of ten *C. volutator* were exposed to a blank control (natural sediment and filtered seawater with no LVE). Sediment (organic content: 2.7%, silt fraction: 68%) was homogenized before preparing the test sediment and each test concentration was prepared by the following procedure. The appropriate amount of test substance was dissolved in about 5 mL of acetone; this solution was added to about 44 g of pre-dried sediment. After the acetone had dried off in a fume cupboard, the sample was added to approximately 500 g of damp sediment in a plastic bucket. One hundred and thirty (130) mL of seawater was added to each bucket and the buckets were shaken (100 rpm) for about 24 hours. The sediment was split into three beakers, 400 mL of seawater was added to each, and the beakers were aerated overnight in a climate controlled room at 15°C . The sediment in the blank controls was treated like the test sediment but without adding the LVE. Over the course of the study, temperature ranged from $13.7 - 16.0^\circ\text{C}$ and dissolved oxygen saturation ranged from 91 – 105%. At the start of the study, the pH was 8.1. The seawater used in this study had a salinity of 33.6 ‰. Percent mortality at 0 (control), 5.4, 10.3, 17.8 and 34.9 mg/kg dry weight was 3.3%, 10%, 35%, 80% and 100%, respectively. Based on nominal concentrations, the 10-day LC50 was 10.4 mg a.i./kg sediment dry weight and the 10-day NOEC was 4.9 mg a.i./kg sediment dry weight. This is an acceptable study.

10-day LC50 = 10.4 mg a.i./kg sediment dry weight

10-day NOEC = 4.9 mg a.i./kg sediment dry weight

(3) Environmental Enterprises USA, Inc. conducted a 7-day survival, growth and fecundity test in mysids (*Mysidopsis bahia*) with L-14-0047 [REDACTED] under semi-static conditions with daily renewal. This study was reported to follow EPA-821-R-02-014: Method 1007. *M. bahia* (number of organisms not specified) were exposed to a negative control (synthetic seawater; five replicates) or the test substance (five replicates) prepared as water accommodated fractions (WAFs) at nominal concentrations of 0.0005, 0.0050, 0.0500, 0.5000 and 1.0000 parts per quadrillion (ppq). A stock solution of 5 g test substance per one thousand milliliters dilution water was prepared in a sealed 2 L glass flask and mixed for 24 hours on magnetic stirrers using ½" diameter by 3" long stir bars. The depth of the vortex of the mixing stock solution was adjusted to approximately 1/3 the total depth of the solution. After mixing for 24 hours, each treatment was allowed to settle for 60 minutes. After settling, the test material (WAF) for each treatment was siphoned from approximately 1.5" below the dilution water surface: the interface of the water soluble and insoluble fraction. An aliquot of this stock solution was diluted with synthetic seawater until a 0.625 ppt stock solution was prepared. This stock solution was used daily to prepare test concentrations. The test temperature was maintained at $25 \pm 1^\circ\text{C}$. Dilution water salinity was 25 ‰. Survival and growth of *M. bahia* larvae exposed to the test substance was not reduced significantly at any concentration tested. The 7-day NOEC and LOEC values were 1.0000 ppq WAF and > 1.0000 ppq WAF, respectively, for both survival and growth. This is not an acceptable test for several reasons. It is not clear why 1.0 ppq was the highest concentration tested. Appendixes A-E were not provided with the submission to determine the water chemistry values, dry weight values, summary statistics, preparation of the test concentrations, etc. They are reported to be in the appendixes. It is not possible to accept only part of this data. Forty eight hour EC50 values were not reported within this 7 day study report. Since a 7 day ecotoxicity study is not a chronic study for OCSPP, the LOEC and NOEC were not used for chronic endpoints.
7-day NOEC (survival and growth) = 1.0000 ppq WAF
7-day LOEC (survival and growth) > 1.0000 ppq WAF

Algal Ecotoxicity Test:

Eurofins Norsk Miljøanalyse AS conducted a 72-hour growth inhibition test in marine algae (*Skeletonema costatum*) with L-14-0047 [REDACTED] under static conditions. This study was reported to follow ISO 10253:2006(E): "Water quality – Marine algal growth inhibition test with *Skeletonema costatum* and *Phaeodactylum tricornutum*". Following preliminary tests, three replicates of *S. costatum* (2500 cells/mL) were exposed to the test substance as water accommodated fractions (WAFs) at nominal concentrations of 0.5, 1.0, 2.0 and 3.4 mg/L. Additionally, six replicates were exposed to a blank control (growth medium with no added chemicals). The algae were illuminated with a light intensity greater than 50 $\mu\text{E}/\text{m}^2/\text{sec}$ with constant shaking. WAFs were prepared individually by stirring appropriate amounts of the test substance in growth medium (according to ISO 14442:2006(E): Water quality – Guidelines for algal growth inhibition tests with poorly soluble materials, volatile compounds, metals and waste water). The solutions were stirred with a spin-bar for 22 hours at a speed which formed a vortex one-third of the depth of the fluid content, followed by a standstill for about 1.5 hours. Closed aspirator bottles were used, and samples for testing were drawn off through a drain port near the bottom of the bottle. Over the course of the study, temperature ranged from 19.2 – 22.9°C and pH was maintained at 8.2. Dilution water had a salinity of 33.3‰. The cell density in the control group increased by a factor of greater than 16 within 72 hours. Treatment with the test substance resulted in 100% inhibition of growth at all test concentrations. The 72-hour EL50 was less than 0.5 mg/L WAF (lowest concentration tested); the NOEL could not be determined (< 0.5 mg/L WAF). This is not an acceptable study since all organisms at all test concentrations stopped growing before the end of the test. EPA recommends initially to conduct a range finding study prior to future definitive toxicity test concentration determinations.
72-hour EL50 < 0.5 mg/L (WAF)
72-hour NOEC (growth rate) < 0.5 mg/L (WAF)
72-hour LOEC (growth rate) = 0.5 mg/L (WAF)

Resman USA (sponsor) submitted five complete or partially complete ecotoxicity studies on L-14-0047. One of the five studies was considered acceptable. Due to the sparingly soluble nature of L-14-0047, the testing laboratory conducted WAF testing for four out of five of their ecotoxicity tests. None of the results from the submitted ecotoxicity studies will be used for the purposes of hazard characterization and COC determination. While the sediment study is considered

acceptable, the chronic and acute COCs are currently based on adverse effects in the water column. Therefore, the QSAR predictions will be used to calculate the chronic and acute COCs. The QSAR predicted acute fish, acute Daphnia, and algae L/EC50s for L-14-0047 are 1.3 mg/L, 0.23 mg/L, and 0.29 mg/L, respectively. The predicted chronic values for fish, Daphnia, and algae are 0.26 mg/L, 0.046 mg/L, and 0.22 mg/L, respectively. The acute concentration of concern (COC) for L-14-0047 is 46 ppb (230 ppb / 5 (uncertainty factor)), based on the QSAR 48-hour EC50 for aquatic invertebrates. The chronic COC for L-14-0047 is 5 ppb (46 ppb / 10 (uncertainty factor)), based on the QSAR chronic value for aquatic invertebrates.

Acute COC = 46 ppb
Chronic COC = 5 ppb

Ecotox Reviewer by J. Gallagher
Date: 12/5/2013

Ecotox Factors:

Assessment Factor: 10
Concern Concentration: 5

V. Summary of Exposures/Releases

Engineering Summary: L-14-0047

Exposures/Releases	Release	Release	Release
Scenario	Use: Tracer Chemical in Oil and Gas Wells	Use: Tracer Chemical in Oil and Gas Wells	Use: Tracer Chemical in Oil and Gas Wells
Sites	124	124	124
Media	Incineration	Deepwell Injection	Water
Descriptor A	Output 2	Output 2	Output 2
Quantity A (kg/site/day)	2.3E-1	5.0E-5	1.4E-6
Frequency A (day/year)	350	350	350
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From	Release to Refinery from Separation Process	Release to Water or Land from On-Shore Separation Process	Release to Water or Land from On-Shore Separation Process
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	Release	Release	Exposure
Scenario	Use: Tracer Chemical in Oil and Gas Wells	Use: Tracer Chemical in Oil and Gas Wells	Use: Tracer Chemical in Oil and Gas Wells
Sites	124	124	124
Media	Landfill	Water or Landfill	Dermal
Descriptor A	Output 2	Output 2	High End
Quantity A (kg/site/day)	8.3E-6	1.0E-4	1.7E-1
Frequency A (day/year)	350	350	250
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From	Release to Water or Land from On-Shore Separation Process	Equipment and Storage Tank Cleaning	Equipment and Storage Tank Cleaning
Workers			992
Exposure Type			Liquid

V. Summary of Exposures/Releases

Engineering Summary:

Exposures/Releases			
Scenario			
Sites			
Media			
Descriptor A			
Quantity A (kg/site/day)			
Frequency A (day/year)			
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From			
Workers			
Exposure Type			

VI. Focus Decision and Rationale

Regulatory Actions

Regulatory Decision: LVE Grant

Decision Date: 12/09/2013

Type of Decision:

Rationale: L-14-0047/49 was granted. Human health hazard concerns were low-moderate for dermal and inhalation exposures. Potential risks to workers were mitigated by negligible exposures. Ecotoxicity hazard concerns were high based on submitted test data. Potential risks to the environment were low due to no exceedances of the COC during the release period. This LVE was not bound at 60 kg/yr and was assessed at 10,000 kg/yr. This LVE is used as a tracer in fracking.

COC: Chronic – 5 ppb, Acute – 46 ppb

Summary of Exposures and Releases

Proc

9 sites, 250 days/yr, 0 workers

Inhalation: Not Expected

Dermal: Non-Quantifiable

Use

124 sites, 350 days/yr, 992 workers

Inhalation: Negligible (VP < 0.001 torr)

Dermal: 1.7E-1 mg/day

Releases to Water: 1.4E-6 kg/site-day over 350 days/yr

Releases to Water: 1.0E-4 kg/site-day over 350 days/yr

Or Landfill

Releases via Incineration: 2.3E-1 kg/site-day over 350 days/yr

Releases via Landfill: 8.3E-6 kg/site-day over 350 days/yr

Releases to Deepwell Injection: 5.0E-5 kg/site-day over 350 days/yr

Fate Releases to Water (0% Removal)

SWC: 9.53E-02 ppb

DW: LADD: 6.83E-08 mg/kg/day, ADR: 4.35E-06 mg/kg/day

FI: LADD: 5.06E-09 mg/kg/day, ADR: 2.83E-07 mg/kg/day

P2 Rec Comments:

Testing:

Final Recommended:

Health:

Eco:

Fate:

Other: